REMARKS

A. Status of the Claims and Explanation of the Amendments

Original claims 1-43 have been cancelled, and claims 44-85 are currently under examination.

Claims 44-69, 71, 76-77, 79, and 84-85 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al. ("Rothbard").

Claims 70 and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 4,725,609 to Kull, Jr ("Kull").

Claims 72 and 80 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 5,785,978 to Porter et al., ("Porter").

Claims 73 and 81 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 5,902,593 to Kent et al. ("Kent").

Claims 74 and 82 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 5,637,316 to Ribier ("Ribier").

Claims 75 and 83 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 4,933,172 to Clark, Jr. ("Clark").

B. Applicants' Claims Are Patentable Over the Cited References

Applicants respectfully traverse the rejection of claims 44-85 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the cited references. Briefly, none of the references, alone or in combination, teach or suggest "[a] topical composition consisting essentially of...a vasodilating amount of a polymer...and a cosmetically or dermatologically

acceptable vehicle" as recited in Applicants' claims. Because not all claim elements are taught or suggested, the rejection of claims 44-85 should be withdrawn. MPEP § 2143.

1. Rothbard Does Not Teach or Suggest the Claimed Invention

Rothbard is directed to methods and compositions for enhancing transport across biological membranes involving a two-component system. More specifically, these methods and compositions involve the use of a non-covalent combination of the delivery-enhancing transporter **and** a biologically active agent [Rothbard, ¶ [0044]]. In certain embodiments, the delivery-enhancing transporter can be polyarginine, [Rothbard, Figures 1 and 2, ¶ [0048]]. According to Rothbard, the purpose of the delivery-enhancing transporter is to "increase delivery of the compound or agent with which the delivery-enhancing agent is combined" [Rothbard, ¶ [0047]].

In contrast, Applicants' independent claim 44 is directed to a composition "consisting essentially of...a vasodilating amount of polymer, and...a cosmetically or dermatologically acceptable vehicle." As explained in MPEP § 2111.03, the "consisting essentially of" language limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics of the claimed invention" [citing *In re Herz,* 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in the original)]. The "basic and novel" characteristics of the claimed invention are determined by looking at the applicant's claims and specification. See, e.g., *AK Steel Corp. v. Sollac*, 344 F 3d 1234, 1239 (stating that "to determine [the basic and novel] properties, we need look no further than the patent specification").

In this case, Applicants' specification states that the arginine oligomers enhance keratin tissues "by enhancing vasodilation through production of nitric oxide" [specification, page 5, first full paragraph]. This property of Applicants' claimed arginine oligomers is also reflected in the claims themselves. For example, independent claims 44 and 56 read as follows:

> 44. A topical composition consisting essentially of (a) a **vasodilating** amount of a polymer having from 7 to 15 subunits, each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine **wherein said polymer increases vasodilation** and (b) a cosmetically or dermatologically acceptable vehicle.
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> 56. A topical composition consisting essentially of (a) a **vasodilating** amount of a polymer having from 7 to 15 subunits, each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine, said polymer further consisting of one or more additional amino acids other than L-arginine, providing that the L-arginine subunits are contiguous and situated at either the C-terminus or the N-terminus of the polymer, **wherein the polymer increases vasodilation** and (b) a cosmetically or dermatologically acceptable vehicle.

Thus, Applicants respectfully submit that the basic and novel characteristics of Applicants' invention include the use of arginine oligomers for enhancing vasodilation through production of nitric oxide to achieve a therapeutic or cosmetic benefit. Rothbard, which does not recognize that arginine oligomers can have any therapeutic benefit in and of themselves, only uses the arginine oligomers as transport carriers of a distinct "biologically active agent."

To the extent that the Examiner takes the position that Rothbard's disclosure of polyarginine as a delivery-enhancing transporter is sufficient to render Applicants' claimed polyarginine oligopeptides obvious, Applicants respectfully disagree. Neither Rothbard nor any of the other cited references teach or suggest the vasodilating biologic activity of oligoarginine

disclosed and claimed by Applicants. Thus, none of the cited publications teach or suggest the use of oligoarginine on its own to achieve a desired biologic effect other than promoting transport of some other biologically active compound. In addition, there is no teaching or suggestion in Rothbard, or any of the other cited references, to modify the non-covalent, two-component conjugates discussed in Rothbard by omitting the biologically active agent and using the only the transport polymer to achieve a beneficial result. See MPEP § 2143.01 (requiring the prior art to suggest the desirability of the claimed invention). Furthermore, even if the Examiner could point to such a teaching, the use of Rothbard's transport polymers for therapeutic purposes themselves would impermissibly change the principle of their operation, as Rothbard teaches that they are only used for transport. See MPEP § 2143.01(VI) (requiring that the proposed modification cannot change the principle of operation of a reference).

Additionally, it appears that Rothbard would teach away from using arginine oligomers in topical compounds for vasodilation. For example, Figure 1 of Rothbard shows a non-covalent complex of a heptamer of L-arginine and taxol. As the Examiner is undoubtedly aware, taxol is a widely used anti-cancer drug for treating lung, ovarian, and breast cancers, all of which involve the presence of a tumor. One of ordinary skill in the art would expect that any cancer treatment, such as the proposed non-covalent complex shown in Figure 1of Rothbard, would not promote vasodilation, because vasodilation in the tumor area would bring blood to the tumor and encourage its growth. Indeed, many anti-cancer compounds are thought to inhibit tumor growth by decreasing blood supply to starve the tumor of nutrients (e.g., angiogenesis inhibitors). Thus, one of ordinary skill in the art, after reading Rothbard, would believe that arginine oligomers would not increase vasodilation, in contrast to Applicants' claimed invention.

For at least these reasons, the rejection of claims 44-69, 71, 76-77, 79, and 84-85 as being unpatentable over Rothbard should be withdrawn. Applicants respectfully request reconsideration and withdrawal of the rejection of these claims.

2. Applicants' Claims Are Patentable Over Rothbard in Combination with the Cited Secondary References

The Examiner attempts to arrive at the subject matter covered in Applicants' dependent claims by combining Rothbard with a variety of secondary references (i.e., Kull, Porter, Kent, Ribier, and Clark). In each case, the Examiner combines Rothbard with a secondary reference that describes a substance to be used as a "biologically active agent" in Rothbard's non-covalent conjugate. For example, in the proposed combination of Rothbard with Kull, the biologically active agent for promoting angiogenesis is nicotinamide (see Kull, col. 1, lines 1-10 and Office Action, page 9, wherein it refers to Kull's description of the topical delivery of an "agent"). Thus, in each of these combinations of Rothbard with a secondary reference, the resulting system is a two-component non-covalent conjugate.

In contrast, Applicants' claim 44 recites "[a] topical composition consisting essentially of...a vasodilating amount of a polymer [of L-arginine or a physiologically acceptable salt thereof]...and a cosmetically or dermatologically acceptable vehicle." Unlike Rothbard's embodiments that include L-arginine oligomers, Applicants' inventive compositions do not require an additional biologically active agent. Simply the fact that the Examiner must resort to a combination of agents to produce an effect achieved by Applicants using arginine alone further confirms the non-obviousness of Applicants' claimed invention.

For at least these reasons, Applicants respectfully assert that the rejections involving Rothbard in combination with a secondary reference, as set forth on pages 8-18 of the of the Office Action dated March 24, 2006, should be withdrawn. Applicants respectfully request reconsideration and withdrawal of these grounds of rejection.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13720-105110US1.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No.13720-105110US1.

Respectfully submitted,
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